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(54) INTRAOCULAR LENSES

(71) I, CHARLES D. KELMAN, of 73 Bacon Road, Old Westbury, Nassau, New York, United States of America, a citizen of the United States of America, do hereby declare the invention, for which I pray that a Patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:–

This invention relates to intraocular lenses suitable for use as artificial lens implants.

Lens implantation is a surgical technique which has come into increasing use for the correction of aphakia resulting from the surgical extraction (either extracapsular or intracapsular) of the natural lens from the patient's eye because of a blindness-causing condition such as cataract. In general format, an intraocular lens consists of a medial lens body about 4 mm in diameter and a plurality of lateral lobes usually projecting from different sides of the lens body for use in fixing the lens in position in the eye.

As is well-known to those skilled in this art, even though the diameter of the lens body of an intraocular lens is only about 4 mm, for the purpose of a lens implantation, a corneo-scleral incision considerably longer than the lens body diameter, and normally from about 8 to 9 mm in length, is required. An incision of this magnitude is mandated because the incision must be capable of being spread far enough to accommodate both the thickness and the width of the lens. In this context, "thickness" means the dimension of the lens as measured from the anteriormost plane in which any part of the lens structure (e.g. the apex of the lens body) is found, to the posterior-most plane (e.g. the plane of the position fixation elements). "Width" means the minimum length of a projection of the lens onto a plane parallel to the optical axis of the lens body, in a direction perpendicular to a projection of the optical axis on such plane, which can be achieved by rotating the lens 360° about said optical axis.

According to the present invention there is provided an intraocular lens suitable for use as an artificial lens implant, in which the lens has a medial, light-focusing lens body, and a pair of lateral position fixation elements connected with said lens body, a first of said position fixation elements having a first portion connected to and extending generally laterally outwardly from a first region of the periphery of said lens body, and a second portion extending from said first portion generally transversely thereto and at least partly peripherally of said lens body, said second portion having that part of its peripheral edge which faces said lens body spaced from the periphery of said lens body, and the second of said position fixation elements extending generally laterally outwardly from a second region of the periphery of said lens body spaced from and generally opposite said first region and in a direction generally opposite to that of said first portion of said first position fixation element, the configurations of said position fixation elements and their location with respect to said lens body being such that the minimum length of a projection of the entire lens onto a plane parallel to the optical axis of said lens body in a direction perpendicular to a projection of said optical axis on such plane which can be achieved by rotating the lens 360° about said optical axis, is greater than the minimum length of a projection of said lens body onto said plane in a direction perpendicular to a projection of said optical axis on such plane which can be achieved by rotating said lens body 360° about said optical axis, to an extent sufficient that insertion of the lens, through an incision in the eye, by a movement which is generally radial with respect to said optical axis would require the length of such incision to be greater than the minimum possible length of the incision which, as a function of the thickness and width of said lens body, would accommodate and permit passage therethrough of said lens body alone, the maximum dimensions of each of said position fixation elements at any part thereof being such that the element can be accommodated in and pass longitudinally through said minimum length incision in the

eye, and said second portion of said one position fixation element having the middle region of that part of its peripheral edge which faces away from said lens body disposed closer to said lens body than the opposite end regions of that edge, the ends of said second portion of said one position fixation element and said tip end region of said other position fixation element providing a three-point support for positioning the lens in the eye.

The present invention is an intraocular lens construction which is characterized by a medial lens body and only two position fixation elements projecting from spaced, generally opposite lateral regions of the lens body. One of these elements has a first portion extending generally laterally from the lens body and a second portion extending from the end of the first portion generally transversely thereto and at least partly peripherally of the lens body, while the other element extends generally laterally from the lens body. The maximum dimensions of any portion of either position fixation element are such that it can be accommodated in and pass through the minimum length incision which is required to accommodate and permit passage of the lens body. Preferably, both elements are unitary with the lens body, i.e. they are not separately attached elements but are formed with the lens body (by molding or machining, for example) of a single block of any suitable physiologically inert and non-toxic synthetic plastics material such as are well known to the art, e.g. polymethylmethacrylate, but the position fixation elements may, as long as they have the requisite shapes and orientations, be constituted by platinum-iridium or equivalent metal wire loops.

The first portion or leg of the first position fixation element which is connected to the lens body, extends (as stated above) generally laterally of the lens body, while the transverse second portion of the element extends from the leg or first portion at least partly peripherally of the lens body. The said second portion must, however, be at a spacing from the periphery of the lens body sufficient easily to accommodate the thickness of the cornea and sclera of the eye, and preferably its circumferential length will be sufficient for it to extend through an arc of between about 40° and about 60° along the periphery of the lens body, with the opposite extremities of the second portion of the first position fixation element as viewed in the plane of the periphery of the lens body being, respectively, located on two imaginary lines which are tangent to the lens body at opposite edges thereof and intersect at a point spaced from the lens body on the side opposite to that where the first position fixation element is located.

The second position fixation element, when made of plastics and located so as to seat either behind or in front of the iris in the upper region of the cul-de-sac of the anterior and posterior capsules, may be provided with means for enbling it to be sutured to the iris to achieve complete immobilization although this is not essential. Such means will preferably consist of an aperture provided within the confines of the element, but as an alternative a pair of notches could be provided on opposite side edges of the element.

In use, when a lens according to the present invention is being implanted, the surgeon will first make a corneo-scleral incision in the eye only slightly longer than the diameter of the lens body, i.e. the incision will be about 5 mm in length. In order to insert the lens into the eye, the surgeon will then introduce the lens essentially "longitudinally" into the eye, i.e. he will in effect snake the lens in through the incision, starting with the free end extremity of the transverse second portion of the first position fixation element and ending with the tip of the second element, until the lens is properly positioned in the eye. This means that the second portion of the first position fixation element is seated adjacent the iris, that the lens body is properly centered in the region of the pupil, and that the second position fixation element (sutured to the iris, if necessary) is seated adjacent the upper region of the iris. It will be understood that the two position fixation elements, upon implantation of the lens, will cooperate to maintain the proper disposition of the lens body relative to the pupil of the eye.

In an intraocular lens according to a preferred embodiment of the present invention, which is particularly suited for an implantation in which the first and second position fixation elements are to be seated in front of the iris in the lower and upper regions, respectively, of the groove located behind the sclerol spur, the two position fixation elements are not entirely coplanar with each other. In this lens construction, both the first portion or leg of the first position fixation element and an inner first section of the second position fixation element, while extending generally laterally from the lens body, also are inclined somewhat posteriorly of the lens body, and the transverse second portion of the first fixation element and the outer or second section of the second position fixation element are generally coplanar with each other, in a plane parallel to the posterior surface plane of the lens body, assuming the latter surface to be flat which will generally be the case. It is contemplated that the degree of the said inclination of the first portion of the first position fixation element and the first section of the second

position fixation element should be such that the perpendicular distance from the common posterior plane of the second portion of the first position fixation element and the second section of the second position fixation element to the posterior surface plane of the lens body is between about 0.25 and 0.75 mm and preferably about 0.5 mm. Additionally, the second or transverse portion of the first position fixation element preferably will have a slight degree of concavity in the plane of the second portion, with a radius of curvature of about 180 mm, in that edge thereof which faces away from the lens body, so that at the opposite ends of the said second portion there will be defined respective radially outwardly directed lobes or tip regions which, upon implantation of the lens (by means of a "snaking in" procedure as previously described), will coact with the tip end region of the second section of the second position fixation element, when the same are all received in the groove behind the scleral spur, to effect an essentially three-point support of the lens in the eye. The arrangement may be such that a small gap will be maintained between the region of the anterior surface of the iris bounding the pupil and the posterior surfaces of the first portion and first section of the first and second position fixation elements, so as to avoid possible irritation of the iris in that region.

The foregoing and other objects, characteristics and advantages of the present invention will be more clearly understood from the following detailed description thereof when read in conjunction with the accompanying drawings, in which:

Fig. 1 is a plan view of an intraocular lens according to an embodiment of the present invention;

Fig. 2 is a side view of the lens shown in Fig. 1; and

Fig. 3 is a diagrammatic vertical section through a human eye and shows a lens according to the embodiment of Figs. 1 and 2 implanted in the eye, the lens being shown in a section taken along the line 9-9 in Fig. 1.

Attention is directed to our copending application no. 80.12207 (Serial No. 1 591 878) divided herefrom, which discloses an intraocular lens similar to that of the present invention. The general operating procedures described in that application are applicable to the present invention and will not be repeated here.

Referring to the drawings an intraocular lens 28 is designed for implantation anteriorly of the iris. As shown in Figs. 1 and 2, the lens 28 (like the lenses shown in Figs. 1 to 6 of our aforesaid application no.) includes a medial light-focusing lens body 29 having a convex anterior surface 29a and a flat posterior surface 29b, a first position fixation element 30 and a second position fixation element 31.

The position fixation element 30, like the element 12, has a first portion 30' extending generally laterally from one region of the periphery of the lens body 29 and a second portion 30" extending generally transversely from the end of the portion 30' and at least partly peripherally of the lens body. Unlike the first and second portions of the element 12 of our aforesaid application no., however, the portions 30' and 30" of the position fixation element 30 are not coplanar with each other or the lens body. Rather, as shown in Fig. 2, the first portion 30' is inclined somewhat posteriorly of the lens body from the region of its connection to the same, and the second portion 30" is disposed entirely posteriorly of the lens body and in a plane generally parallel to the plane of the lens body. Also, the transverse second portion 30" of the second position fixation element 30 is somewhat concavely curved on its outwardly facing edge 30a, as shown in Fig. 1, for example at a radius of curvature of about 180 mm, thereby to define at its opposite ends respective radially outwardly directed lobes or tip regions 30b and 30c.

Correspondingly, the second position fixation element 31 extends generally laterally from a second region of the periphery of the lens body spaced from and generally opposite the region where the first portion 30' of the first position fixation element 30 is located. The element 31 is not coplanar with the lens body but as shown in Fig. 2, the position fixation element 31 has a first inner section 31' which is inclined somewhat posteriorly of the lens body 29 from the region of its connection to the same, and a second outer section 31" which is disposed entirely posteriorly of the lens body and in a plane generally parallel to the plane of the lens body.

Although by virtue of the foregoing arrangement the two position fixation elements 30 and 31 are not coplanar with the lens body, the degree of inclination of the first portion 30' of the first position fixation element 30 and the degree of inclination of the first section 31' of the second position fixation element are, respectively, such as to dispose the second portion 30" of the first position fixation element and the second section 31" of the second position fixation element in coplanar relation with each other and with their posterior surfaces at a perpendicular distance J of about 0.25 to 0.75 mm from the posterior surface 29b of the lens body 29. By virtue of this arrangement, therefore, when the lens 28 has been implanted in a human eye, as shown in Fig. 3, the lens body 29 and the proximate por-

tion 30' and section 31' of the two position fixation elements will be maintained out of contact with the iris 20 in the region of the pupil, thereby to minimize the possibility of the lens irritating the iris and interfering with the expansion and contraction of the pupil 22.

Referring again to Fig. 1, it will be seen that the second section 31" of the position fixation element 31 is provided adjacent its outer extremity with a small aperture 32, generally about 0.15 mm in diameter. In this case, however, the aperture is not a suturing hole but rather is provided only to facilitate manipulation of the lens during the insertion thereof into the eye.

It will be apparent from the foregoing that the insertion of the lens 28 through the corneo-scleral incision in the eye will be effected in the same manner, i.e. by a "snaking in" procedure, as is described in connection with Figs. 5 and 6 for the lens 10 of our aforesaid application no., and the details of that description thus need not be repeated at this point. The ultimate position of the lens 29 will be different, however, in that the entire lens is positioned anteriorly of the iris, with the second portion 30" of the first position fixation element 30 and the second section 31" of the second position fixation element 31 seated in the lower and upper regions 33 and 34, respectively, of the groove behind the scleral spur 35. It can also be seen that by virtue of the provison of the lobes 30b and 30c on the portion 30" of the position fixation element 30, the same will coact with the lobe or tip end 31a of the second section 31" of the position fixation element 31 to provide a three-point support for the lens in the eye so as to maintain the lens body in proper position relative to the pupil of the eye.

Yet another advantage of a lens 28 according to this embodiment of the present invention is that for any given implantation operation, the selection of a lens having a vertical dimension which is precisely equal to, or in any event not greater than, the available space between the top and bottom lobe-seating regions of the groove behind the scleral spur of the patient's eye is not a matter of critical concern for the surgeon. In this context, by "vertical dimension" is meant the perpendicular distance between a plane tangent to the downwardly convex edge regions of the lobes or tips 30b and 30c of the second portion 30" of the first position fixation element 30 and a parallel plane tangent to the upwardly convex edge region of the lobe or tip 31a of the second section 31" of the second position fixation element 31. Thus, in the lens 28 the medial transverse width of the second portion 30" of the position fixation element 30 can be sufficiently reduced, for example by a suitable choice of the degree of concavity of the edge 30a, that if the surgeon happens to have used a lens which is slightly oversized by, say, a half millimeter or so with respect to the aforesaid available space in the eye, the portion 30" will be able to flex upwardly a little so as to adapt itself to the eye without placing undue stresses on, and perhaps even damaging, the tissues in the groove. The same type of upward flexure may also be accommodated by a suitable choice of the transverse width of the end region of the first portion 30' of the position fixation element 30 where that portion joins the second portion 30". If desired, of course, the contemplated upward flexure capability may be achieved by an appropriate conjoint utilization of both these approaches.

WHAT WE CLAIM IS:–

1. An intraocular lens suitable for use as an artificial lens implant, in which the lens has a medial, light-focusing lens body, and a pair of lateral position fixation elements connected with said lens body, a first of said position fixation elements having a first portion connected to and extending generally laterally outwardly from a first region of the periphery of said lens body, and a second portion extending from said first portion generally transversely thereto and at least partly peripherally of said lens body, said second portion having that part of its peripheral edge which faces said lens body spaced from the periphery of said lens body, and the second of said position fixation elements extending generally laterally outwardly from a second region of the periphery of said lens body spaced from and generally opposite said first region and in a direction generally opposite to that of said first portion of said first position fixation element, the configurations of said position fixation elements and their location with respect to said lens body being such that the minimum length of a projection of the entire lens onto a plane parallel to the optical axis of said lens body in a direction perpendicular to a projection of said optical axis on such plane which can be achieved by rotating the lens 360° about said optical axis, is greater than the minimum length of a projection of said lens body onto said plane in a direction perpendicular to a projection of said optical axis on such plane which can be achieved by rotating said lens body 360° about said optical axis, to an extent sufficient that insertion of the lens, through an incision in the eye, by a movement which is generally radial with respect to said optical axis would require the length of such incision to be greater than the minimum possible length of the incision which, as a function of the thickness and width of said lens body, would accommodate and permit passage therethrough of said lens body alone,

the maximum dimensions of each of said position fixation elements at any part thereof being such that the element can be accommodated in and pass longitudinally through said minimum length incision in the eye, and said second portion of said one position fixation element having the middle region of that part of its peripheral edge which faces away from said lens body disposed closer to said lens body than the opposite end regions of that edge, the ends of said second portion of said one position fixation element and said tip end region of said other position fixation element providing a three-point support for positioning the lens in the eye.

2. An intraocular lens as claimed in claim 1 wherein said second portion of said first position fixation element is arcuately concave in the middle region of that part of its peripheral edge which faces away from said lens body and is arcuately convex at the opposite end regions of that edge, and said second position fixation element is arcuately convex at that part of its peripheral edge which faces away from said lens body, the convex edge regions of the ends of said second portion of said first position fixation element and the convex edge region of the tip end region of said second position fixation element providing said three-point support.

3. An intraocular lens as claimed in claim 1 or 2 wherein said first portion of said first positon fixation element is inclined posteriorly of said lens body from said first region of said periphery thereof, and said second portion of said first position fixation element is disposed posteriorly of said lens body and in a plane substantially parallel to the plane of said lens body, and wherein said second position fixation element has a first section and a second section, said first section being contiguous with said lens body and inclined posteriorly of the same from said second region of said periphery thereof, and said second section extending from said first section and being disposed posteriorly of said lens body and in a plane substantially parallel to the plane of said lens body.

4. An intraocular lens as claimed in claim 3 wherein said second portion of said first position fixation element and said second section of said second position fixation element are disposed in substantially coplanar relation with each other.

5. An intraocular lens as claimed in claim 4 wherein said second position fixation element is provided, in said second section thereof, with a small aperture to facilitate manipulation of the lens during an implantation operation.

6. An intraocular lens as claimed in claim 4 or 5 wherein the respective inclinations of said first portion of said first position fixation element and said first section of said second position fixation element are such that the common plane of said second portion of said first position fixation element and said second section of said second position fixation element is spaced between about 0.25 mm and about 0.75 mm from said plane of said lens body.

7. An intraocular lens as claimed in any of claims 1 to 6 wherein the medial transverse width of said second portion of said second position fixation element is such that the free end region of said second portion can flex slightly in the direction of said lens body and said second position fixation element.

8. An intraocular lens as claimed in any of claims 1 to 7 wherein the transverse width of said first portion of said first position fixation element is such that said second portion of said one position fixation element can flex slightly in the direction of said lens body and said other position fixation element.

9. An intraocular lens suitable for use as an artificial lens implant substantially as herein before described with reference to and as illustrated in Figures 1 to 3 of the accompanying drawings.

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1591877 COMPLETE SPECIFICATION

1 SHEET *This drawing is a reproduction of the Original on a reduced scale*

Fig.3.

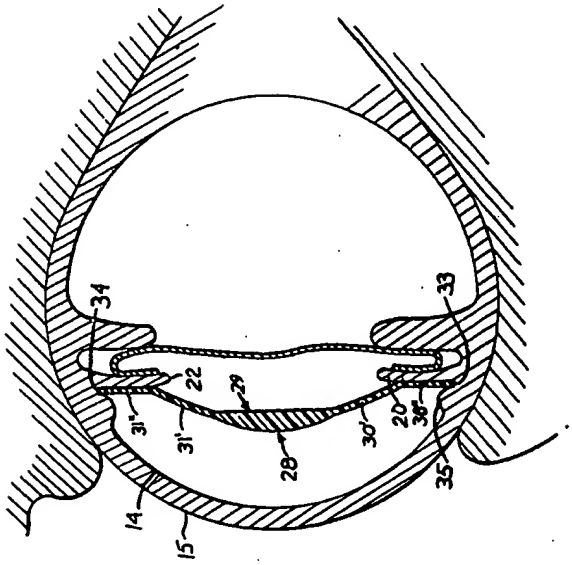

Fig.2.

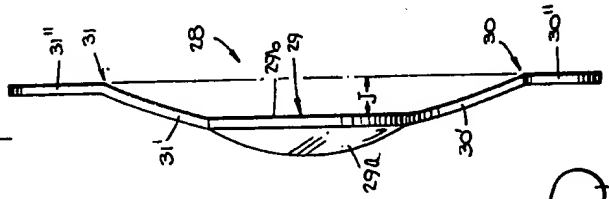

Fig.4.